IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. PRECISION HERBS LLC, ORIGINAL DESIGN WELLNESS CENTER, SHARON OVERMAN, ERIC PIERCE, Defendants.	)	INFORMATION 5:19 MJ 08003 CASE NO. MAG. JUDGE GREENBERG Title 21, United States Code, Sections 331(a), 331(f), and 333(a)(1)

GENERAL ALLEGATIONS

1. The United States Food and Drug Administration (FDA) was the agency of the United States responsible for protecting the health and safety of the public by enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA), Title 21, United States Code, Section 301-399f.

2. Defendant PRECISION HERBS LLC ("PRECISION HERBS") was a company incorporated in the State of Ohio and was in the business of manufacturing and selling drugs and devices in interstate commerce. Specifically, PRECISION HERBS advertised that it manufactured "alcohol-based tinctures, salves and vegetable-based encapsulations of unique herbal formulas," and "construct[ed] electronic devices" that "address[ed] individual wellness needs and improved daily living." PRECISION HERBS also advertised that its intent was "to offer products that worked extremely well, to actually fix numerous health problems."

3. Defendant ORIGINAL DESIGN WELLNESS CENTER was an S Corporation located in Ohio that was associated with PRECISION HERBS and that distributed PRECISION HERBS' products.

4. Defendant SHARON OVERMAN was an owner of PRECISION HERBS and the president and manager of ORIGINAL DESIGN WELLNESS CENTER.

5. Defendant ERIC PIERCE was an owner of ORIGINAL DESIGN WELLNESS CENTER and Chief Operating Officer of PRECISION HERBS.

COUNT 1
(Refusal of Inspection, Title 21, Sections 331(f) and 333(a)(1))

The United States Attorney charges:

6. Paragraphs 1 through 5 are re-alleged and incorporated by reference as if fully set forth herein.

7. Title 21, United States Code, Section 374 authorized the FDA to enter and inspect any factory, warehouse, or establishment in which drugs and devices were manufactured, processed, packed, or held, for introduction into interstate commerce.

8. On or about January 15, 2016, FDA obtained a Warrant for Administrative Inspection from a duly-authorized United States Magistrate Judge in the Northern District of Ohio for (a) PRECISION HERBS, 9804 Township Road 89, Killbuck, Ohio 44637 ("Killbuck facility"); and (b) PRECISION HERBS, 9227 Township Road 82, Millersburg, Ohio 44654 ("Millersburg facility"). ORIGINAL DESIGN WELLNESS CENTER was co-located with PRECISION HERBS and operated out of the Millersburg Facility by OVERMAN and PIERCE.

9. On or about January 21, 2016, FDA investigators, accompanied by United States Marshals, attempted to conduct a for-cause inspection of PRECISION HERBS and ORIGINAL DESIGN WELLNESS CENTER at the locations described in the preceding paragraph.

10. On or about January 21, 2016, OVERMAN and PIERCE refused the inspection of the Millersburg facility after being presented with the warrant and two notices of inspection on FDA Form 482.

11. On or about January 21, 2016, PIERCE initially allowed the inspection at the Killbuck facility until a third party arrived and began to disrupt the inspection of the facility. After being told by a Deputy United States Marshal that allowing the third party to disrupt the inspection would constitute a refusal of inspection, PIERCE allowed the disruption and the inspection was terminated.

12. On or about January 21, 2016, in the Northern District of Ohio, PRECISION HERBS, ORIGINAL DESIGN WELLNESS CENTER, OVERMAN and PIERCE did refuse to permit entry and inspection as authorized by Section 374.

In violation of Title 21, United States Code, Sections 331(f) and 333(a)(1).

COUNT 2

(Introduction of Adulterated Drugs and Devices, Title 21, Sections 331(a) and 333(a)(1))

The United States Attorney further charges:

13. Paragraphs 1 through 5, and 7 through 11 of the Information are re-alleged and incorporated by reference as if fully set forth herein.

14. Title 21, United States Code, Section 331(a) prohibited the introduction or delivery, and causing the introduction or delivery, into interstate commerce of any drug or device that was adulterated.

15. Title 21, United States Code, Section 321(g) defined "drug" to include articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; articles (other than food) intended to affect the structure or any function of the body; or articles intended for use as a component of those products.

16. Title 21, United States Code, Section 321(h) defined "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease; intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary purpose.

17. Under Title 21, United States Code, Section 351(j), a drug or device was "adulterated" if it was manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of said location delayed, denied, or limited an inspection, or refused to permit entry or inspection by FDA.

18. After the refusal of inspections described in paragraphs 8-11, from on or about January 21, 2016, until on or about May 24, 2017, in the Northern District of Ohio and elsewhere, PRECISION HERBS, ORIGINAL DESIGN WELLNESS CENTER, OVERMAN, and PIERCE introduced and caused the introduction of drugs and devices into interstate commerce, to wit: Activase, Harmonic Transmitter, Overcoming Parasites Naturally, Blood Pressure Reg., Fertilized Viability, Puricell, Skel-Norm, and Magna-Zap, which were adulterated in that they were manufactured, processed, packed, and held in any factory, warehouse, and establishment and the owner, operator, and agent of said location refused to permit inspection by FDA.

In violation of Title 21, United States Code, Sections 331(a) and 333(a)(1) .

JUSTIN E. HERDMAN
United States Attorney

By: Robert W Kern
ROBERT W. KERN
Chief, White Collar Crimes Unit